Knockoff Weight Loss Drugs From Illegal Foreign Sources:

An analysis of unauthorized semaglutide and tirzepatide shipments entering the U.S. with urgent recommendations to protect the safety of Americans

George Karavetsos and the Partnership for Safe Medicines

The Partnership for SAFEMEDICINES®

Table of contents

Executive Summary

Availability of compounded versions of GLP-1s has exploded in the U.S. despite warnings from the U.S. Food and Drug Administration (FDA) that they are not FDA-approved, lack the safety and efficacy assurances of the approved medicines, and shouldn't be used when the approved medicine is available.[1] Claims have been made about their effectiveness in advertising as prominent as the Super Bowl with no clear explanation to Americans about their problematic safety profile.[2]

Americans, on the whole, do not understand what it means for a medicine to not carry FDA-approval, or have no FDA assurance of safety or efficacy—a fact we confirmed in a recent public opinion poll about Americans' knowledge and opinions of compounded drugs.[3] As FDA has explained, compounded GLP-1 products "can be risky for patients." Inspections have found compounding pharmacies operating under poor conditions that have led to patient illnesses and death.[4] And there are reports of contaminated, counterfeit, and subpotent GLP-1s from many sources.[5]

The origin of the active ingredients (also known as active pharmaceutical ingredients or API) used in compounded GLP-1s has also become a primary source of concern and criticism. Indeed, 93% of respondents in our public opinion poll were concerned about knockoffs from unknown or uncertain places of origin, like China. Compounders are required to obtain their API from FDA-registered facilities,[6] and both FDA[7,8] and the branded GLP-1 manufacturers[9,10] have expressed concern that some drug compounders use API from unauthorized foreign sources.

1. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss
2. https://abcnews.go.com/GMA/Wellness/super-bowl-ad-hims-weight-loss-drug-sparks/story?id=118695064
3. https://www.safemedicines.org/wp-content/uploads/2019/09/PSM-Poll-Summary-of-Findings.pdf
4. https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers
5. https://www.reuters.com/business/healthcare-pharmaceuticals/lilly-finds-bacteria-other-impurities-mounjaro-zepbound-knockoffs-2024-03-07/; https://www.forbes.com/sites/tylerroush/2024/05/30/ozempic-maker-novo-nordisk-sues-pharmacies-and-weight-loss-clinics-for-allegedly-selling-impure-drugs/; https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness; https://abc11.com/post/how-lose-weight-abc-news-tests-potent-online-compounded-drugs-like-ozempic-wegovy-mounjaro-zepbound/15586570/
6. We note that FDA-registration is merely one aspect of the regulatory process, and that many registered foreign API manufacturers have not been inspected by FDA.
7. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prorx-llc-696742-12202024
8. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss
9. https://www.novonordisk-us.com/media/news-archive/news-details.html?id=168519,
10. https://investor.lilly.com/news-releases/news-release-details/lilly-commends-itc-ruling-cracking-down-unlawful-importation-and

We wanted to better understand the nature of bulk API that might be used by both licensed and unlicensed/illegal compounders. We downloaded and analyzed records of shipments into the U.S. maintained by U.S. Customs and Border Protection (CBP) and compared them to lists of legitimate, FDA-registered establishments that have listed a semaglutide or tirzepatide product with FDA, as required by law to legally import any API into the U.S.

After studying 2,465 shipments from September 2023 to January 2025, we identified 239 problematic shipments of semaglutide or tirzepatide that were from unregistered entities that do not have any semaglutide or tirzepatide products listed with FDA. Many of these shipments were allowed to enter the U.S. anyway, a violation of federal law. Sixty of these shipments originated from China or Hong Kong, 42 from India, and 49 from Canada.

Especially disturbing were the number of shipments explicitly marked for compounding.

This is a disturbing quantity of semaglutide and tirzepatide API coming into the U.S. from unauthorized sources, which has the potential to harm many Americans. While we acknowledge the resource issues associated with ensuring border security and pharmaceutical supply chain integrity, our review of the relevant data shows that FDA and CBP know how to stop these products—and in fact does so sometimes. We recognize those efforts and urge them to do more to keep Americans safe from unregulated and illicit foreign API.

With that in mind, we call upon:

- Compounders to be more transparent with consumers about the source of their APIs;
- FDA to add these rogue foreign API manufacturers to the Import Alert system to flag future shipments;
- FDA and CBP to increase interdictions of these unauthorized shipments; and
- FDA and State Boards of Pharmacy to prioritize inspections of and take appropriate enforcement action against compounders when unauthorized foreign API manufacturers attempt to ship unauthorized API to them.

Background

A key concern underlying the proliferation of compounded drugs, in particular GLP-1s for the treatment of diabetes and obesity, is API being used to make them. There are several concerns about the quality and safety of APIs, especially when they're intended to be used in sterile injectables. Injectables with even a small issue with consistency, purity, or sterility can be dangerous and possibly life threatening.

- **API for use in sterile drug products and contamination concerns:** Injectable drug products, like those made from semaglutide and tirzepatide, must be sterile. Failure to ensure API used in these products is appropriate for sterile injectable drugs could result in microbial contamination making its way into the finished product and could result in serious harm to patient health.[11,12] This contamination can happen during the API creation process, during the compounding process when using contaminated API, or from sterility issues in the compounding process itself.[13] FDA has previously warned compounders to use ingredients suitable for sterile compounding.[14] It has also cautioned that failure to ensure sterility could lead to serious patient injury or death.

- **Lack of purity / additional, unwanted substances:** Chemical suppliers providing API to compounders have produced products with extraneous substances in them. It can be challenging to avoid introducing unwanted substances when making drug substances, which is why FDA-inspected manufacturers put an enormous amount of time and resources into achieving pure and unadulterated medicines. It is common for cleaning solvents to be found in products made by unregulated facilities because those facilities fail to properly remove the solvents as part of the process of cleaning their chemical-making equipment.[15] Injecting oneself with cleaning chemicals that "ride along" with non-FDA-approved medications can have serious health consequences.

- **Correct and consistent quantity within the API:** Clear and consistent dosing is important to ensure a drug is efficacious and safe, and inconsistent levels of API may

11. See, for example, this warning from November 2024: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness
12. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/fagron-group-bv-624255-06142022
13. https://www.raps.org/News-and-Articles/News-Articles/2015/12/Compounders-Beware-API-from-China-May-Be-Contamin
14. https://www.fda.gov/drugs/human-drug-compounding/fda-reminds-compounders-use-ingredients-suitable-sterile-compounding
15. https://www.sciencedirect.com/science/article/abs/pii/S0731708513001416

create a risk of overdosing or underdosing. While the human danger of an overdose is well known, underdosing is also a patient hazard. Many patients work with their physicians to find the right dose to achieve therapeutic effects. If patients can't rely on consistent levels of API in their medication, they cannot effectively manage their disease and may be exposed to harms of underdosing or overdosing.

Currently, many users of compounded GLP-1s are under minimal physician supervision via telehealth platforms. This situation makes it particularly difficult to identify dosing errors since patients often have no regular relationship with the prescribing physician, if there's even follow up with them at all.

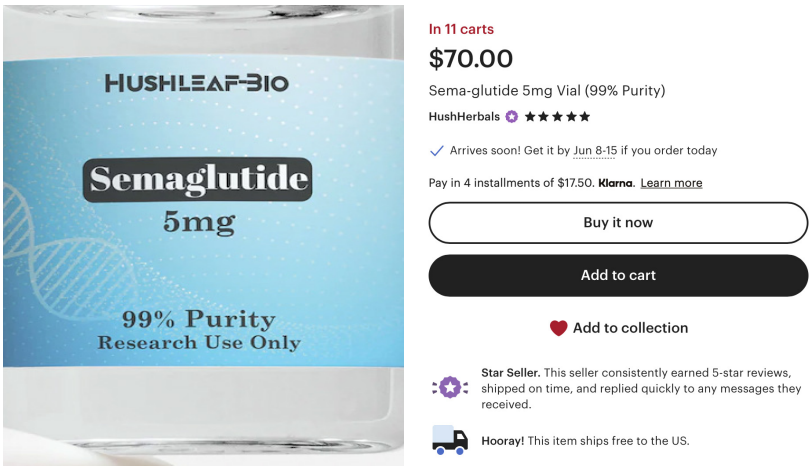
Research-grade vs. for human use API

Study of consistency, purity, and sterility of pharmaceutical manufacturing is an entire industry unto itself, and beyond the scope of this paper. It's critical, though, to highlight one major issue: Research-grade chemicals, sometimes sold as "research use only" products, do not meet the standard for use in humans.

We've seen a spike in criminals selling American patients research-grade semaglutide and tirzepatide. These products should never be administered to humans. Unfortunately, these products are widely available and advertised with the expectation, and sometimes explicit instructions, that they will be injected in the same way as the FDA-approved medications.[16] These products are not just available through unscrupulous online sellers. Doctors in Ohio were recently disciplined because they were giving patients weight loss drugs labeled "For Research Use Only" that they obtained from an unlicensed seller.[17] Two medspas in Tennessee were recently part of an enforcement action for purchasing research-use only product from an unlicensed seller and administering them to patients.[18]

16. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/xcel-research-llc-694608-12102024, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/summit-research-peptides-695607-12102024, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prime-vitality-inc-dba-prime-peptides-695156-12102024
17. https://ohiocapitaljournal.com/2025/01/28/two-ohio-doctors-and-their-clinics-disciplined-over-weight-loss-drugs/
18. https://www.nbcnews.com/health/health-news/tennessee-woman-accused-selling-fake-weight-loss-drugs-counterfeit-con-rcna184154

FDA has also warned that research grade chemicals should not be used in compounding GLP-1s after sending warning letters to two companies that were marketing them to patients.[19]



This research-grade chemical was one of many examples on Etsy that we covered in our Public Safety Alert in March 2024.

Foreign made GLP-1 APIs and drug compounding

The branded semaglutide (Ozempic, Wegovy, and Rybelsus) and tirzepatide (Mounjaro and Zepbound) manufacturers have repeatedly stated that they are not supplying bulk API to compounders in the U.S. Most registered suppliers of bulk API that could be used for compounding are located abroad. Additionally, most of the bulk product companies in the U.S. that have registered with FDA to make bulk semaglutide or tirzepatide API are only in the repackaging or relabeling space — they do not manufacture bulk API themselves. And one of the few U.S.-based entities registered to manufacture semaglutide or tirzepatide, a company called nomida.biz, received a very serious FDA warning letter last year and appears to have ceased operating.[20] That means most of the bulk API for GLP-1s must be coming from overseas.

Because the ingredients for legally and illegally compounded versions of GLP-1s sold to U.S. patients are very likely imported from foreign sources, we wanted to know:

19. https://www.google.com/url?q=https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss&sa=D&source=docs&ust=1739752983891449&usg=AOvVaw1W-uqTWJSoZ35X8UX5BuDM
20. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/nomidabiz-687590-09122024

- Where are they coming from?
- Has unauthorized semaglutide and tirzepatide API been entering the country and, if so, should it have been caught and stopped?

Our analysis shows there is a significant amount of unauthorized GLP-1 API entering the country that should have been refused.

Smuggling has been a known problem in the Chinese chemical industry for years, and was just cited by President Trump in a recent Executive Order on fentanyl smuggling by vendors in the People's Republic of China (PRC):

> ***Many PRC-based chemical companies also go to great lengths to evade law enforcement and hide illicit substances in the flow of legitimate commerce. Some of the techniques employed by these PRC-based companies to conceal the true contents of the parcels and the identity of the distributors include the use of re-shippers in the United States, false invoices, fraudulent postage, and deceptive packaging.***[21]

Our analysis makes clear that President Trump's concerns about Chinese chemical companies going to great lengths to evade law enforcement and import illicit substances into the U.S. marketplace should extend beyond fentanyl to API that is being used in diabetes and weight-loss products sold to Americans every day. This serious threat to America's safe medicine supply warrants urgent attention from both federal and state governments and compounders.

21. https://www.whitehouse.gov/presidential-actions/2025/02/imposing-duties-to-address-the-synthetic-opioid-supply-chain-in-the-peoples-republic-of-china/

Methodology and Data Sources

To understand the scale of the problem, we examined FDA import records using the FDA's data from September 1, 2023 through January 31, 2025 for shipments of semaglutide and tirzepatide. We studied 2,465 total import records, looking for issues that would indicate that unregulated semaglutide or tirzepatide ingredients may be entering the country. As we studied them, we were focused on three things:

- **FDA Establishment Identifier (FEI):** This is an ID number used in FDA communications to uniquely identify people and firms associated with regulated drug products. It's easy to obtain an ID number and does not mean you are authorized or inspected to make drug products. You can look up FEI numbers in the FDA's FEI Search Portal (registration and use is free but requires a login).

- **Drug Establishment Registration System:** This is a database of drug establishments registered with FDA. Any facility making products for the U.S. market is required to be a registered drug establishment. If any entity is not registered as a drug establishment, FDA does not know that the entity is making drug products and needs to be inspected. It also means any products from the unregistered entity cannot be imported into the U.S. You can look these up in the FDA DECRS system.

- **NDC Unfinished Drug Products Database:** The NDC database describes the drug product, the dosage, other information (if relevant), and the manufacturer of drug products listed with FDA. You can look up NDC codes in the FDA's NDC Search portal. Search "Unfinished drug products," then select "non-proprietary name," then enter "semaglutide" or "tirzepatide" to follow our work.

We compared the manufacturer's FEI listed in the import record and their address to the information in FDA's FEI Search Portal. We then checked DECRS to see if that entity was registered as a drug establishment. Finally, we used the FDA's NDC Unfinished Drug Products Database to see if the API manufacturer in the import data had listed a semaglutide or tirzepatide product with FDA in the NDC Unfinished Drug Products Database.

The import records themselves told us many things about how each shipment was handled by FDA – including whether it was released into the U.S. or refused – and if FDA conducted additional screening.

It's important to note FDA and CBP records do not indicate the destination or source mailing entity or address so we cannot make conclusions about how the API was used.[22] However, as we discuss in the findings section, shipments are regularly labeled as "for Rx compounding" (or similarly descriptive language), and FDA has repeatedly warned compounders they are not allowed to use API from unregistered sources.[23]

We partnered with George Karavetsos, an expert in FDA law enforcement, to guide our research, analysis, and findings, leveraging his experience as the former head of FDA's Office of Criminal Investigations, a federal prosecutor, and Assistant Chief Counsel of FDA.

We deeply appreciate the work FDA and CBP do to keep dangerous products out of the U.S. With George's experience having worked for FDA and as PSM has featured and trumpeted the work of both agencies, our observations are designed to expose the troubling vulnerabilities detected in the security of our drug supply chain and potential for serious harm it can cause to consumers.

22. The lack of access to this information is of great frustration to rightsholders of commonly counterfeited products, as this prevents them from investigating illicit supply chains. We understand that for a variety of reasons it is not likely to change soon.
23. https://www.fda.gov/media/104822/download (observation 9); https://www.fda.gov/files/about%20fda/published/AnazaoHealth-Corporation--Las-Vegas--NV--483-Issued-1-30-2015.pdf (observation 9); https://www.fda.gov/media/158758/download (observation 7); https://www.fda.gov/media/130443/download (observation 11); https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/pharmaceutical-care-solutions-dba-pharmacy-solutions-610201-08022021; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/belmar-pharma-solutions-drug-depot-llc-dba-aps-pharmacy-653740-03312023; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prorx-llc-696742-12202024

Findings

Unauthorized manufacturers are shipping semaglutide and tirzepatide API into the U.S. and some are succeeding.

We found 199 shipments of semaglutide imports from manufacturers that had no registered drug establishment with FDA, meaning that FDA has no idea they should be inspecting them. We confirmed they also had no semaglutide product listed with FDA in the NDC Unfinished Products Database. Nearly 80% of these shipments were admitted into the U.S.

We found 40 shipments of tirzepatide imports from manufacturers that were not registered in DECRS. They also had not listed any tirzepatide product with FDA in the NDC Unfinished Products Database. Again, that means FDA is not aware of their operations or their intent to make these ingredients. Almost all (90%) of these were admitted into the U.S.

Substance	Shipments of product made by facilities that do not have a registered drug establishment	Allowed in / Turned away
Semaglutide	199 shipments	159 / 40
Tirzepatide	40 shipments	36 / 4

If a manufacturing facility is not registered with FDA, it cannot be inspected and the safety of products made with its ingredients is suspect. Any shipments of API from unregistered foreign manufacturers are unlawful and should be refused at the border. Equally important: It is illegal to use materials from an unregistered facility in any drug products for American patients, including compounded drugs.

Unauthorized imported API is being used in compounded GLP-1s

The data does not indicate where these bulk API shipments were sent, so we cannot identify who received the shipments. But we know these unsafe products entered the country, and almost all were specifically declared for human use.

Overall, 25 of the 40 unsafe shipments of tirzepatide and 17 of the 199 unsafe shipments of semaglutide were explicitly marked as either "Rx API for Compounding" or indicated for "Further Manufacturing". As a reminder, none of these ingredient suppliers have registered as drug establishments so the FDA would not be aware of their operations. That means they simply are not fit for legal drug compounding.

Products with disqualifying descriptions are being shipped into the U.S. and some are sneaking by.

Imports are accompanied by a product code that tells FDA the purpose of the product. While many importers choose the vague but allowed phrase, "Not Elsewhere Classified", others are very clear. The explanations, combined with what the product is, sometimes paint a picture of a product that absolutely should not be allowed in the U.S. — and yet, too often these products are still allowed in. Here are some examples we saw that concern us:

"Non-sterile" API

As a human injectable, finished versions of semaglutide or tirzepatide must be sterile. Using a non-sterile ingredient to prepare a sterile injectable is challenging enough that we question how this can possibly be safe. Any semaglutide or tirzepatide API marked "non-sterile" should be carefully scrutinized, especially from an unregistered facility that hasn't informed the FDA they're making these products.

Two shipments of semaglutide marked 'non-sterile' were stopped, yet several shipments of non-sterile semaglutide and tirzepatide were allowed into the U.S. without any inspection or further investigation.

Arrival Date	Country of Origin	Product Description	Product Code Description	Manufacturer Legal Name	Manufacturer City Name	Manufacturer Country	Disposition meaning
09/17/2024	Netherlands	Rx Single Ingredient Non-Sterile Liquid	TIRZEPATIDE	VITAL PHARMATECH CO., LTD	Zhuhai	China	Shipment was released with comment after being detained by the FDA
06/18/2024	China	Rx Single Ingredient Non-Sterile Powder	TIRZEPATIDE	HUBEI FORTUNE PHARMACEUTICAL CO	Wuhan	China	FDA release issued at time of entry review without conducting any type of physical filed examination or sample collection

Arrival Date	Country of Origin	Product Description	Product Code Description	Manufacturer Legal Name	Manufacturer City Name	Manufacturer Country	Final Disposition Date	Disposition
11/29/2024	Bangladesh	Rx Comination Ingredient - Non-Sterile Liquid	SEMAGLUTIDE	BALY ENTERPRISE DISTRIBUTOR	Dhaka	Bangladesh	06/07/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
01/03/2025	Brazil	Rx Comination Ingredient - Non-Sterile Liquid	SEMAGLUTIDE	PATRICIA DE VITO FUHRMANN	Jaru	Brazil	10/02/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
01/06/2025	Canada	Rx Comination Ingredient - Non-Sterile Liquid	SEMAGLUTIDE	KAREN JATTANA	Burnaby	Canada	01/30/2025	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
12/20/2024	China	Human Investigation - Non-Sterile Powder	SEMAGLUTIDE	SHENZHEN JYMED TECHNOLOGY	Shenzhen	China	12/17/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
10/29/2024	China	Human Investigation - Non-Sterile Powder	SEMAGLUTIDE	SHENZHEN JYMED TECHNOLOGY	Shenzhen	China	12/17/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
09/11/2024	France	Rx Single Ingredient – Non-Sterile Liquid	SEMAGLUTIDE	ZENTIVA	Paris	France	11/11/2023	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
06/20/2024	India	Rx Single Ingredient – Non-Sterile Powder	SEMAGLUTIDE	APOTHECON PHARMACEUTICALS PVT. LTD	Padra	India	07/02/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
09/08/2023	Mexico	Rx Single Ingredient – Non-Sterile Liquid	SEMAGLUTIDE	NOVO NORDISK SERV PROF S A DE CV	Polando	Mexico	12/15/2023	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
01/06/2024	Philippines	Rx Comination Ingredient - Non-Sterile Liquid	SEMAGLUTIDE	MARIA APOLONIA M CHIPADA	Camaman-An-Gagayan De	Philippines	05/09/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
02/22/2024	Canada	Non Rx Single Ingredient - Non-Sterile Liquid	SEMAGLUTIDE	ELIE PHARMACY	Elie	Canada	04/11/2024	The FDA denied entry of the shipment after export
09/11/2024	Israel	Rx Single Ingredient - Non-Sterile Liquid	SEMAGLUTIDE	PRESCRIMEDS	Ashkelon	Israel	12/04/2023	The FDA denied entry of the shipment after export
09/18/2024	Canada	Rx Single Ingredient - Non-Sterile Liquid	SEMAGLUTIDE	PARKWAY PHARMACY	Winnipeg	Canada	12/27/2024	Shipment was released with comment after being detained by the FDA

Non-approved forms of products (suppositories and ointments)

There are no approved versions of GLP-1 medicines in the U.S. that come as a suppository or ointment, and yet semaglutide products marked as such were released into the U.S. without any additional examination. While we understand the resource limitations of inspecting packages physically, these could have been rejected purely on the advanced electronic data showing them to be a misbranded product.

Arrival Date	Country of Origin	Product Description	Product Code Description	Manufacturer Legal Name	Manufacturer City Name	Manufacturer Country	Final Disposition Date	Disposition
04/27/2024	Mexico	Rx Single Ingredient - Sterile Ointment	SEMAGLUTIDE	NOVO NORDISK MEXICO S.A. DE C.V.	Tlalnepantla De Baz	Mexico	04/17/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
09/09/2024	Brazil	Rx Single Ingredient - Suppositories	SEMAGLUTIDE	Novo Nordisk Producao Farmaceutica	Montes Claros	Brazil	08/10/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection

"Investigational" products are not unregulated

We saw a disturbing number of foreign shipments of semaglutide and tirzepatide API declared as intended for human investigational purposes. Identifying API as part of an "investigational trial" is not a magic wand that allows unregistered rogue foreign manufacturers to bypass U.S. customs laws. Clinical trials must be registered with FDA and anyone importing drug products for such trials must provide the number of a valid investigational new drug application (IND) authorizing the clinical trial. While it can be legal to import products for "laboratory use," FDA knows bad actors are selling "research use only" semaglutide and tirzepatide for human use and has done admirable work with the Department of Justice protecting the public from them.[24,25,26]

24. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/warrior-labz-sarms-655280-06122023
25. https://www.safemedicines.org/wp-content/uploads/2019/09/Information.pdf
26. https://www.safemedicines.org/2024/10/plea-jeremy-brown.html

Accordingly, all "investigational" shipments designated for laboratory use warrant heightened scrutiny and should not be admitted unless the importer establishes a legitimate investigational use and the quantities being imported align with laboratory analysis (as opposed to illegal mass sale to unsuspecting consumers). However, in only one case below did FDA seek additional paperwork used before releasing these products. In several cases the products were released into the U.S. without any further investigation.

Country of Origin	Product Description	Product Code Description	Manufacturer Legal Name	Manufacturer City Name	Manufacturer Country	Final Disposition Date	Disposition Meaning
China	Human Investigational Small Volume Parenteral	TIRZEPATIDE	HIKMA CANADA LIMITED	Mississauga	Canada	01/10/2025	FDA release issued at time of entry review without conducting any type of physical filed examination or sample collection
China	Human Investigation Sterile Powder	TIRZEPATIDE	ZHEJIANG MEDICINES & HEALTH PROD	Hangzhou	China	10/23/2024	FDA release issued at time of entry review without conducting any type of physical filed examination or sample collection
China	Human Investigation Sterile Powder	TIRZEPATIDE	ZHEJIANG MEDICINES & HEALTH PROD	Hangzhou	China	09/05/2024	FDA release issued at time of entry review without conducting any type of physical filed examination or sample collection
China	Human Investigation Sterile Powder	TIRZEPATIDE	ZHEJIANG MEDICINES & HEALTH PROD	Hangzhou	China	01/27/2025	FDA release issued at time of entry review without conducting any type of physical filed examination or sample collection
China	Human Investigational API for Rx Compounding	TIRZEPATIDE	HANGZHOU THINHEAL PHARMA-TECH CO	Hangzhou	China	11/14/2024	FDA release issued at time of entry review without conducting any type of physical filed examination or sample collection
China	Human Investigational API for Rx Compounding	TIRZEPATIDE	JYMED YECHNOLOGY	Shenzhen	China	02/22/2024	Shipment was released after being detained by the FDA
China	Investigational API for Further Manufacturing	TIRZEPATIDE	SHANDONG MORESHINE BIOTECH CO.,LTD	Shandong Province	China	09/13/2024	Shipment was released after being detained by the FDA
China	Human Investigational NEC	TIRZEPATIDE	VITAL PHARMATECH CO., LTD	Zhuhai	China	11/14/2024	Released after obtaining an investigator's brochure from the manufacturer. The IB contains a description of the drug and its formulation, a summary of the pharmacological and toxilogical effects, and information pertaining to safety, effectiveness, side effects, and other information.

Arrival Date	Country of Origin	Product Description	Product Code Description	Manufacturer Legal Name	Manufacturer City Name	Manufacturer Country	Final Disposition Date	Disposition
12/05/2024	China	Human Investigational - Sterile Powder	SEMAGLUTIDE	ZHEJIANG MEDICINES & HEALTH PROD	Hangzhou	China	09/05/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
10/23/2024	India	Investigational - Small Volume Parenteral	SEMAGLUTIDE	Orbicular Pharmaceutical Tech Pvt Ltd	Hyderabad	India	11/18/2024	FDA release issued at the time of entry review without conducting any type of physical field examination or sample collection
10/06/2024	Brazil	Investigational - Sterile Liquid	SEMAGLUTIDE	RIO BIOFARMA BRASIL LTDA	Hortolandia	Brazil	1/30/2025	The shipment was released

Implausible "manufacturing sites" shipping into the U.S.

The paperwork accompanying foreign-manufactured API often contains red flags that could easily be detected by minimal due diligence, such as manufacturer names or addresses that are objectively unlikely to be legitimate. Here are some examples we saw that concern us:

JW Marriott in Vancouver, Canada.

On March 29, 2024, a shipment of semaglutide arrived for entry into the U.S. The listed manufacturer on the manifest is a JW Marriott (a hotel) at 39 Smythe St, Vancouver, Canada. This is a photo of that location on Google Maps.

The JW Marriott actually has an FDA Establishment Identifier (FEI) on the shipping manifest, which is a sign that anyone can get FEI. However, the hotel is not registered with FDA as a drug establishment. We would have been surprised if JW Marriot had registered as a drug establishment. This shipment was refused entry to the U.S., but many equally suspect shipments were admitted.

National Gym and Fitness Center in Etobicoke, Canada

On Oct. 27, 2024, a shipment of semaglutide was presented for entry that listed National Gym and Fitness Center as its manufacturer. The gym at the listed address of 220 Humberline Dr., Etobicoke, Canada, appears to be a real gym with an Internet presence and photos submitted by customers to Google Maps:

While the National Gym and Fitness Center also has an FDA Establishment Identifier, it is not registered with FDA as a drug establishment. The shipment was allowed into the U.S. without any physical examination.

Ursula Franklin Academy in Toronto, Canada

On June 23, 2024, a shipment of "semaglutide - tablets" was presented for entry into the U.S. with the manufacturer labeled as Ursula Franklin Academy in Toronto, Canada. This is a 500-person public school in Toronto that looks like this on Google Maps:

Ursula Franklin Academy is not registered with FDA as a drug establishment. The shipment was released into the U.S.

> *"PSM respects and appreciates the FDA and CBP's obligation, without discretion, to protect Americans from unsafe, unchecked products coming into the country from foreign sources. Despite their efforts, far too many suspicious shipments are making their way into the country. We call on the agencies to use the tools at their disposal to assure the American public that their weight loss drugs are safe. Similarly, we call on drug compounders, including medspas and telehealth companies, to operate with transparency, integrity, and responsibility to their customers."*
>
> **– Shabbir Safdar, Executive Director, Partnership for Safe Medicines**

"Under the law, the FDA is required to block shipments of pharmaceutical ingredients from unregistered manufacturing facilities at the border. Yet this report shows dangerous, unchecked drug ingredients are entering the U.S. in large numbers bound for use in compounded and counterfeit products. U.S. law enforcement and regulators must ensure Americans are not exposed to the dangers of illegal drug ingredients from foreign sources."
– George Karavetsos, former director of FDA's Office of Criminal Investigations and federal prosecutor."

Urgent Recommendations to Protect the Safety of Americans

Compounders of GLP-1 medicines[27] should disclose the FDA-registered manufacturer of their API to their customers as a minimal assurance of legitimacy. Typically, a Certificate of Analysis, which isn't even included by all compounding vendors, doesn't identify the FDA-registered manufacturer of the bulk API. It should.

There is significant and concerning activity of criminals attempting to ship unapproved semaglutide and tirzepatide, some of it marked for compounding, into the U.S. Because we've seen significant patient endangerment from illegal sales of research chemicals, and FDA has warned about compounding GLP-1s with unapproved ingredients, compounders should be doing everything possible to provide assurances to their customers that they are using ingredients from authorized manufacturers registered with FDA. Even those assurances cannot guarantee that the compounded products are safe or that they will work as intended, but patients should demand (and should be entitled) to see that the ingredients being used are coming from FDA-registered facilities.

FDA must refuse entry to any drugs that "appear" to be misbranded, adulterated, or otherwise unapproved.[28]

As our data shows, FDA and CBP often refuse unsafe medical products and we acknowledge the good work they have done in this area in our public communications frequently.

We urge FDA/CBP to continue this good work. Section 801(a) of the Food, Drug and Cosmetic Act requires FDA to refuse admission to any drug product that "appears" to be misbranded, adulterated, or otherwise unapproved. The use of the word "appears" was not accidental in this statute. The risk of harm to patients from unregulated ingredients is so great that the drafters wanted to err on the side of caution and put the onus to prove that

27. This is not a broad recommendation for all compounded medicines, just GLP-1's which are experiencing an explosion in both popularity and fraudulent criminal activity.
28. 21 USC 381 (a) ("If it appears from the examination of such samples or otHerwise that" the imported drug violates certain requirements, "then any such article … shall be refused admission, except as provided in subsection (b).")

the product is legally entitled to be admitted into the country squarely on the shoulders of the importer. As a result, if a foreign API manufacturer even appears to lack registration, FDA must refuse the shipment.

FDA should add these and any other rogue manufacturers to the Import Alert watch list. FDA has a robust system for flagging problematic companies attempting to import their products into the U.S. called the "Import Alert"[29] system. We screened the FDA's Import Alert system and found that two of the vendors in these problematic shipments have been subject to import alerts dated Feb. 7, 2025, and Jan. 13, 2025.

The other unregistered foreign API manufacturers found in these shipping records have not registered a drug establishment with FDA. Yet many of them have repeatedly shipped their unapproved products into the U.S., where they put American patients at risk.

All the rogue manufacturers identified herein, and any others that emerge later, should be added to the alert system.

FDA and state boards of pharmacy should prioritize inspections of compounders that attempt to import GLP-1 API from unregistered facilities.
We are pleased to see that FDA has warned multiple compounders that unlawfully use bulk API from unauthorized sources. Based on our analysis, more resources are needed for this essential work.

Compounders, both 503A and 503B, that attempt to import bulk semaglutide and tirzepatide from unregistered facilities should be prioritized for immediate inspection by their respective regulatory authority, FDA or state board of pharmacy. Any entity that is purchasing API from unregulated facilities for use in human drugs is acting unlawfully, and such disregard of the law raises suspicions about the integrity of the compounder's operations generally.

29. https://www.fda.gov/industry/actions-enforcement/import-alerts

FDA must refuse shipments if their shipping information and labeling does not meet regulatory requirements.

FDA regulations require that importers provide a "product code" that matches the drug's description and intended use. The code will reveal whether it is a finished drug product and how it should be labeled. Examples of problematic products that could be detected, even without laying hands on the box, are listed above. Upon inspection of either the manifest or the product itself, if it is not labeled correctly, federal law requires that it be refused.

To view the data used in our analysis and to learn more about GLP-1 patient safety, visit safemedicines.org.

Shabbir Imber Safdar has served as the Executive Director of the Partnership for Safe Medicines since 2017. He previously worked as PSM's Director of Outreach and consulted with the organization for nearly a decade. Shabbir is passionate about patient safety and the dangers of counterfeits, having seen examples first-hand in countries around the world where a closed, secure drug supply chain doesn't exist.

Comprised of more than 45 non-profit organizations, PSM is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard, or otherwise unsafe medicines. Founded in 2003, PSM focuses on researching the danger of counterfeit drugs in America and educating the public about how to stay vigilant.

George Karavetsos is a former director of the FDA's Office of Criminal Investigations, where he led a team of over 300 federal law enforcement agents in investigating violations of the Federal Food, Drug, and Cosmetic Act (FDCA). In this role, he established the FDA's criminal enforcement priorities, overseeing cases involving pharmaceutical and medical device companies, food and dietary supplement manufacturers, and other regulated industries. Prior to that, he served as an assistant chief counsel in the FDA's Office of the Chief Counsel, handling complex regulatory, compliance, and enforcement matters.

Before his tenure at the FDA, George was a federal prosecutor for over a decade, handling high-profile cases involving healthcare fraud, FDCA violations, and other white-collar crimes. His combined experience in FDA regulation and criminal enforcement gives him a deep understanding of the risks associated with the importation of compounded drug ingredients and the challenges of ensuring drug safety and supply chain integrity.